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| APPLICATION NO.   | FILING DATE    | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|-------------------------|---------------------|------------------|
| 09/677,737  | 10/02/2000     | Curtis Cole             | JBP525              | 3415             |
| 7:  | 590 06/04/2003 |                         | •                   | •                |
| Philip S Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 |                |                         | EXAMINER            |                  |
|   |                |                         | YU, GINA C          |                  |
|   |                |                         | ART UNIT            | PAPER NUMBER     |
|   |                |                         | 1617                |                  |
|   |                | DATE MAILED, 06/04/2003 |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   | Application No.  | Applicant(s)  |  |  |  |
|--|---|--|---|--|--|--|
| Office Action Summary  |   | 09/677,737   | COLE ET AL.   |  |  |  |
|  |   | Examiner   | Art Unit  |  |  |  |
| <u> </u>   |   | Gina C. Yu   | 1617  |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |   |  |  |  |
| THE I - External form - If the - If NO - Failu - Any r   | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.15 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing ad patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day fill apply and will expire SIX (6) MONTHS from Cause the application to become ARANDONE | nely filed s will be considered timely. the mailing date of this communication. |  |  |  |
| 1)[  | Responsive to communication(s) filed on 18 A  | <u>farch 2003</u> .  |   |  |  |  |
| 2a)⊠   | This action is <b>FINAL</b> . 2b) This  | s action is non-final.   |   |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims                  |   |  |   |  |  |  |
| 4)⊠ Claim(s) <u>1-3,5,6 and 9-15</u> is/are pending in the application.  |   |  |   |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |   |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |   |  |  |  |
| 6)⊠ Claim(s) <u>1-3,5,6 and 9-15</u> is/are rejected.  |   |  |   |  |  |  |
| 7) Claim(s) is/are objected to.  |   |  |   |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |   |  |   |  |  |  |
| Application Papers   |   |  |   |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |  |   |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |  |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |   |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.   |   |  |   |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |   |  |   |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.   |   |  |   |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |   |  |   |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |   |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |  |   |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |   |  |  |  |
| 2  | 2. Certified copies of the priority documents have been received in Application No  |  |   |  |  |  |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |   |  |   |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |   |  |   |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |   |  |   |  |  |  |
| Attachment(s)  |   |  |   |  |  |  |
| 2) Notice 3) Informa   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Informal Pa   | (PTO-413) Paper No(s) atent Application (PTO-152)                               |  |  |  |
| J.S. Patent and Trac<br>PTO-326 (Rev.  | 0.4.043   | on Summary   | Part of Paper No. 18  |  |  |  |

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#### **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on March 18, 2003. Claims 1-3, 5, 6, and 9-15 are pending. The claim rejections under 35 U.S.C. § 102 and the rejections under § 103 over Perricone (US 6319942 B1) in view of Lacharriere et al. (US 5968532) as indicated in the previous Office action dated December 18, 2002 are modified to meet the new claim limitations. The claim rejection under 35 U.S.C. § 103 over Toth (WO 009804280 A2) is withdrawn in view of applicants' claim amendment.

### Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-5 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Perricone (US 6365623 B1) ('623).

'623 patent teaches method of treating acne in inflammatory phase by applying a composition comprising lipoic acid and most preferably adjunct ingredients such as 0.5-5 % by weight of methyl or ethyl-aminoalcohols or 0.05-% by weight of tyrosine. See col. 5, lines 30-53; col. 8, lines 41-61; col. 9, lines 16-22; instant claims 1, 4, 11, and 12. The patent specifically states, "one particularly efficacious embodiment of the invention contains lipoic acid, glycolic or lactic acid, and dimethylaminoalcohol; and another further contains tyrosine." See col. 9, lines 21-23. Examiner asserts that the claimed method is anticipated by the specific teaching here.

2. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Perricone (US 6319942 B1) ('942).

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The rejection is maintained for the reasons of record.

In response to applicants' argument that the reference teaches the addition of dimethylaminoethanol and tyrosine as an option, examiner asserts that the teaching specifically indicates that the most preferred embodiment of the invention contains the claimed ingredient.

Applicants also argue that the fact that the formation of scars undergoes inflammatory stage is irrelevant. Examiner respectfully disagrees. The claimed method reads on the prior art method of treating scars undergoing inflammatory stage.

3. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Ptchelintsev (US 5972993).

Ptchelintsev discloses a topical composition comprising 0.5% by weight of triethanolamine, useful in treating rosacea. See col. 10, lines 33-66. The method of using the topical composition is inherent.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 6 and 9-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone '942 as applied to claims 1-3 and 5 above, and further in view of De Lacharriere et al. (US 5968532) ("de Lacharriere").

Perricone '942, discussed above, fails to teach treating redness or inflammation caused by the irritants recited in the instant claims.

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De Lacharriere teaches the method of treating irritant side effects of dermatological compositions. The reference teaches 'dysaesthetic sensations' to generally refer to sensatiosn such as stinging, itching, burning, inflammation, etc. See col. 1, lines 43 – 64. The reference also describes the inflamed skins of sensitivie skin types have sensation of "inflammation, pulling, tingling, and/or redness" by factors such as food, environment and certain cosmetic products. See col. 2, lines 9-14. It is further taught that sensitive scalps undergo sensations of itching, stinging, and/or of inflammations triggered by soap, surfactants, environment, and cosmetic, etc.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of treating scars or inflamed skin condition described in Perricone '942 by applying the composition therein to the reddened or inflamed skin caused by the irritants or damaged by environment as motivated by de Lacharriere. The skilled artisan would have expected that the composition that is effective in treating inflammatory scar wounds would be similarly effective in reducing inflammation or the associated symptoms caused by other factors such as skin irritants.

# Response to Arguments

Applicant's arguments filed March 18, 2003 have been fully considered but they are not persuasive in part and moot in view of new grounds of rejection in part.

Applicants argue that de Laccharriere fails to provide a skilled artisan motivation to extend the Perricone "942 methods to include treating redness or inflammation of skin caused by the claimed skin irritants. Examiner respectfully disagrees. As

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explained in the rejection, de Laccharrier teaches that the recited skin irritants such as soap, surfactants, and cosmetic, cause skin inflammation, whose symptoms include redness, burning sensation, pulling, etc. Given the general teaching in Perricone '942 patent that the recited composition is used in treating inflammation, it would have been obvious to the routineer that the composition would be similarly effective in treating the skin inflammation caused by skin irritants, which also causes similar symptoms.

#### Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu Patent Examiner June 2, 2003

SREENI PADMANABHAN

6/2/03